

**Questions for the Expert Panel Review of the  
Addendum to *In Vitro* Ocular Toxicity Draft Background Review Documents**

1. Is the information provided in the Addendum to the November 2004 BRDs appropriate for inclusion in the accuracy and reliability analyses? Are there any errors or omissions that should be corrected?
2. Based on the revised accuracy and reliability analyses for each *in vitro* test method for identifying ocular corrosives and severe irritants, does this new information provide the basis for any changes in the Panel's conclusions and recommendations made at the January 11-12, 2005 meeting? If so, please describe the changes and the rationale for each.
3. Is the revised list of proposed reference substances, selected from the list of available candidate substances, sufficiently adequate and complete for validation studies to evaluate the usefulness and limitations of *in vitro* test methods proposed for identifying ocular severe irritants and corrosives<sup>1</sup>? If not, please describe any recommended changes and the rationale for each.

---

<sup>1</sup> This list of proposed reference substances is intended to represent the minimum number and types of substances considered necessary to adequately evaluate the usefulness and limitations of *in vitro* ocular irritancy test methods proposed for identifying ocular severe irritants and corrosives. The list represents a broad range of chemical and product classes, and physical/chemical properties. Subsets of substances from this list may be considered for initial assessment of accuracy and reliability, optimization of a test method protocol, validation of test methods that are functionally and mechanistically similar to a validated ocular irritancy test method, proficiency testing to ensure the competency of a laboratory in performing a validated ocular irritancy test method, or for evaluating a test method proposed for identifying substances with a narrower range of defined properties.